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IN THE

Supreme Court of the United States

OCTOBER TERM, 1984

LEE M. THOMAS, ACTING ADMINISTRATOR,
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
Appellant,

v.

UNION CARBIDE AGRICULTURAL PRODUCTS CO., ET AL.

On Appeal from the United States District Court for the Southern District of New York

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BRIEF OF GRIFFIN CORPORATION AND DREXEL CHEMICAL COMPANY AS *AMICI CURIAE* IN SUPPORT OF REVERSAL

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BRIEF OF GRIFFIN CORPORATION AND DREXEL CHEMICAL COMPANY AS *AMICI CURIAE*

INTEREST OF *AMICI CURIAE*

For the second time in two years, large pesticide producers have mounted a constitutional attack on the pesticide registration scheme established by the Federal Insecticide, Fungicide, and Rodenticide Act, *as amended*, 7 U.S.C. §§ 136a-136y (1982) ("FIFRA"). Last Term, in *Ruckelshaus v. Monsanto Co.*, 467 U.S. ——, 104 S. Ct. 2862 (1984) (hereafter "*Monsanto*"), this Court upheld the data licensing and disclosure provisions of

FIFRA under the Taking Clause of the Fifth Amendment and determined that a challenge to the statutory compensation provision was not ripe for review. Shortly thereafter, the Court vacated the district court's decision in the instant case, which had enjoined enforcement of the registration scheme. The district court had concluded that the statutory provision for resolution of compensation disputes before an arbitrator violated Article III of the Constitution. This Court directed the district court to reconsider its decision in light of *Monsanto. Ruckelshaus v. Union Carbide Agriculture Products Co.*, 468 U.S. ——, 104 S. Ct. 3566 (1984). On reconsideration, the district court reinstated its original decision and again enjoined enforcement of the registration scheme. J.S. App. 21a-22a.[1]

Griffin Corporation ("Griffin") and Drexel Chemical Company ("Drexel"), both of which are small pesticide producers whose products have been registered or await registration under this statute, file this brief as *amici curiae* in support of the Administrator of the Environmental Protection Agency ("EPA") to illustrate the drastic impact affirmance of the decision below would have on small producers, the American farmer, and the consumer. The Solicitor General and the appellees have consented to the filing of this brief; letters so indicating are being filed with the Clerk.

Griffin is a privately-held Georgia corporation headquartered in Valdosta, Georgia, with additional manufacturing facilities in Texas. Its products are sold primarily in California, Florida and Georgia. Griffin's annual sales volume is approximately $50 million, over half of which derives from the sale of products which are registered

[1] References to the Jurisdictional Statement and its Appendix are cited as "J.S." and "J.S. App." respectively. On October 19, 1984, this Court stayed the district court's injunction. 469 U.S. ——, 105 S. Ct. 237.

under the invalidated scheme. It also has applications for amendments of existing registrations pending with EPA, and anticipates filing ten to twelve additional applications this spring.

Drexel Chemical Company is a Tennessee corporation based in Memphis, Tennessee. Drexel does business primarily in the central and southeastern United States and has annual domestic sales of approximately $30 million. About 50 percent of Drexel's revenues are derived from products registered under the regulatory program invalidated by the district court in this case. Drexel expects to file 15 to 20 applications in the near future.

Griffin and Drexel are typical of small manufacturers and formulators of pesticide products which play a vital role in maintaining competition in the marketplace. Specific examples of the benefits of these companies' market participation are described at pages 18-20 *infra*.

FIFRA requires marketers of pesticide products to obtain a registration from the EPA before the product can be marketed in the United States. § 3(a), 7 U.S.C. § 136(a). EPA bases its decision to register a product, in part, on test data intended to show that the pesticide will not cause "unreasonable adverse effects on the environment." §§ 3(c)(5)(C)&(D), 7 U.S.C. §§ 136a(c)(5)(C)&(D); *Monsanto*, 104 S. Ct. at 2867-68. Assembling such data is a costly and time consuming process.[2] As a result, if each producer were compelled to generate its own test data in order to obtain the regulatory license

[2] EPA recently found that the 1980-81 cost of the testing necessary to support a registration was approximately $1.9 million to $2.8 million per active ingredient. EPA, REGULATORY IMPACT ANALYSIS: DATA REQUIREMENTS FOR REGISTERING PESTICIDES UNDER THE FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT 14-15, 70, 72 (1982). The Senate Committee on Agriculture, Nutrition, and Forestry's 1977 estimate of the testing cost per pesticide was $7 million. S. REP. No. 334, 95th Cong., 1st Sess. 30 (1977).

to market a pesticide, only firms with large financial resources, like the appellees in this case, could surmount the costly barriers to market entry erected by the regulatory scheme.

In 1972, Congress sought to minimize these regulatory market entry barriers by amending FIFRA to allow EPA to consider data submitted by one applicant in support of a second applicant's product containing the same active ingredients.[3] The second applicant still would apply to EPA for a registration, but in doing so could establish the safety of the product by relying on test data submitted by the initial registrant instead of submitting his own data, provided that the second applicant offered to compensate the first applicant for the use of his data. EPA was empowered to fix the amount of compensation, subject to limited judicial review, if the parties were unable to agree on the amount. § 3(c)(1)(D), 86 Stat. 979 (1972); *Monsanto*, 104 S. Ct. at 2868. These procedures allowed small pesticide producers to market products chemically identical to previously registered pesticides without having to duplicate the costly testing process incurred by the original registrant.[4]

Congress again amended § 3(c)(1)(D) in 1975 and 1978,[5] but only the latter amendments are relevant to

[3] Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516, 86 Stat. 973 (1972).

[4] As a practical matter, only unpatented products or pesticides whose patents had expired were eligible for registration by a second applicant without the original registrant's consent. One of Congress' concerns in adopting the 1972 amendments was that a requirement that each applicant submit his own data could effectively extend patent monopolies beyond those authorized by the patent system. *See* S. REP. No. 970, 92d Cong., 2d Sess. 12, 14, 16 (1972), *reprinted in* 1972 U.S. CODE CONG. & AD. NEWS 4092, 4096, 4098, 4100.

[5] Pub. L. No. 94-140, 89 Stat. 751 (1975); Federal Pesticide Act of 1978, Pub. L. No. 95-396, 92 Stat. 819 (1978).

this case. Those 1978 amendments granted to original registrants a 10-year period of exclusive use for data on new active ingredients contained in pesticides registered after September 30, 1978. § 3(c)(1)(D)(i), 7 U.S.C. § 136a(c)(1)(D)(i). All other data submitted after 1969 could be considered in support of a later application. However, if the data were considered in support of a later application within 15 years of its original submission, the second applicant had to offer compensation to the original submitter of the data. Compensation disputes no longer were to be resolved by EPA, but by an arbitrator appointed by the Federal Mediation and Conciliation Service. § 3(c)(1)(D)(ii), 7 U.S.C. § 136a(c)(1)(D)(ii). Data not subject to the 10-year exclusive use or 15-year compensation provisions were open to consideration by EPA in support of a subsequent application without compensation to the original submitter. § 3(c)(1)(D)(iii), 7 U.S.C. § 136a(c)(1)(D)(iii); *Monsanto*, 104 S. Ct. at 2869. Thousands of "follow-on" (also known as "me-too") pesticide products have been registered under this regulatory scheme, and thousands more are expected to be registered if the Court upholds the statute.

Griffin and Drexel joined with several other similarly situated pesticide producers last Term in urging this Court in *Monsanto* to uphold the registration scheme under the Taking Clause.[6] As we pointed out in *Monsanto*, the effect of invalidating the registration scheme under the Taking Clause would have been to drive most small pesticide formulators and producers out of the market because these firms lack the financial resources to assemble the necessary test data on their own. Even as to the few companies that could undertake their own test-

[6] *See* Brief of Pesticide Producers Ass'n et al. as *Amici Curiae*, *Ruckelshaus v. Monsanto Co.*, 467 U.S. ——, 104 S. Ct. 2862 (1984).

ing, the effect of requiring them to do so when EPA already has registered a pesticide with the same active ingredients would be to waste scarce scientific resources and millions of dollars in testing expenditures merely to duplicate the information already in EPA's files.[7] A decision this Term that the FIFRA registration scheme fails to pass constitutional muster under Article III again would thwart Congress' assessment that the public interest warrants increased competition in the marketing of pesticides and elimination of wasteful duplication of testing. The many small pesticide producers and formulators that have flowered under this regulatory program would wither rapidly if the "follow-on" scheme is struck down. The present *amici* accordingly urge the Court again to sustain FIFRA's registration scheme as a valid exercise of congressional authority to balance the benefits and burdens in the marketing of safe pesticide products in United States commerce.

INTRODUCTION AND SUMMARY OF ARGUMENT

We are filing this brief as *amici curiae* not to duplicate the parties' briefs, which undoubtedly will address fully the significant constitutional issues presented by this case, but to outline our position on the issues presented and to call to the Court's attention the practical ramifications of invalidating the entire follow-on registration scheme.

As a threshold matter, there is no greater justification for adjudicating in this case the constitutional validity of the arbitration provision than there was in *Monsanto*. No party in this case has been injured by reason of an arbitration under this statute, and hence the issue is not ripe for review. *Monsanto*, 104 S. Ct. at 2882. Only one of the appellees has even been involved in an arbitration proceeding under this statute; that party currently is

[7] *Id.* at 3-4.

engaged in separate litigation arising out of that arbitration in which it seeks to recover the sum awarded in the arbitration. This appellee's position in that case is inconsistent with its claim of injury here.

Nevertheless, if the Court reaches the merits, nothing in Article III forbids Congress from assigning resolution of compensation disputes arising under this statute to arbitrators, subject to limited judicial review, instead of to federal judges. A compensation claim under FIFRA stems from a right created by Congress, and Congress may assign to particularized non-Article III tribunals the vindication of such statutory rights. In any event, the statute provides for limited judicial review of arbitration decisions before an Article III tribunal to assure the fairness of the proceedings and compliance with the limits of the arbitrator's authority. The Constitution requires no more extensive form of judicial review.

A contrary conclusion on the constitutionality of the arbitration scheme does not justify the broad injunction striking down virtually the entire FIFRA registration scheme which district court ordered. The proper remedy in such a circumstance is either to strike the limitation on judicial review or, at most, the arbitration provision. The former would permit United States district courts to review the lawfulness of arbitration awards under the jurisdiction that would have existed under current law but for the limitation on judicial review. *See* 28 U.S.C. §§ 1331, 1337(a) (1982); FIFRA § 16(c), 7 U.S.C. § 136n(c). The latter would reinstate EPA's responsibility to resolve compensation disputes. Congress itself has directed this finely tuned surgical approach to constitutional adjudication by enacting in FIFRA a severability clause (§ 30, 7 U.S.C. § 136x) establishing a presumption that Congress would have enacted the unobjectionable portion of the statute without the provision found to be unconstitutional. The surviving portions of the statute are fully workable as a regulatory scheme, and their

preservation is consistent with Congress' stated priority that the compensation mechanism not be used to prevent prompt registration of eligible pesticides.

ARGUMENT

I. BECAUSE THE APPELLEES HAVE NOT BEEN INJURED AS A RESULT OF AN ACTUAL ARBITRATION, THE CONSTITUTIONALITY OF THE ARBITRATION PROVISION OF FIFRA IS NOT RIPE FOR REVIEW

The Court held last Term that Monsanto's challenge under Article III to the compensation arbitration provision in § 3(c)(D)(ii) of FIFRA, 7 U.S.C. § 136a(c)(D)(ii), was not ripe for review and that "[o]nly after EPA has considered data submitted by Monsanto in evaluating another application and an arbitrator has made an award will Monsanto's claims with respect to the constitutionality of the arbitration scheme become ripe." *Monsanto*, 104 S. Ct. at 2882. Despite this Court's remand of the district court's earlier decision for reconsideration in light of *Monsanto* (104 S. Ct. 3566), the district court again enjoined the registration scheme on the theory that the arbitration provision violates Article III.

The facts have not changed since this case was last here and the Court vacated the district court's original decision. Only one of the appellees—Stauffer Chemical Company ("Stauffer")—has invoked the statutory arbitration mechanism,[8] and that party, as was true last Term, is a defendant and counterclaimant in separate litigation in the United States District Court for the District of Columbia involving that arbitration. *PPG Industries, Inc. v. Stauffer Chemical Co.*, Civ. Action No. 83-1941 (D.D.C. filed July 7, 1983). There is no reason why Stauffer should be permitted to bifurcate its objections to the arbitration process; it can raise all the constitutional arguments it advances here in the District of Columbia action where they can be addressed in the factual context of an actual arbitration, not, as this Court has described it, "in the rarefied atmosphere of a debating society . . . ." *Valley Forge Christian College v. Americans United for Separation of Church and State, Inc.*, 454 U.S. 464, 472 (1982).

[8] The appellees, other than Stauffer, do not claim that they have participated in or been injured by any FIFRA arbitration. They stand in the same position that Monsanto was in when this Court ruled that the issue is not ripe for review. *See Monsanto*, 104 S. Ct. at 2882.

In any event, Stauffer's present claim of injury from an actual arbitration is inconsistent with its posture in the District of Columbia litigation. Instead of asserting that the award is inadequate, Stauffer has asked the District of Columbia court to enforce the award or, alternatively, to award it damages equal to the arbitration award.[9] Stauffer's position is tantamount to "having its cake and eating it too." It may once have sought a higher award than it received in the arbitration, but in the District of Columbia action Stauffer has acquiesced in the amount awarded by seeking either its enforcement or damages of an equivalent amount.

Given its professed satisfaction with the arbitration award, Stauffer cannot "establish that it had been injured by actual arbitration under the statute." *Monsanto*, 104 S. Ct. at 2882. In the absence of such injury, Article III's requirement of a case or controversy has not been satisfied, and, accordingly, Stauffer lacks standing to

[9] As the Solicitor General has pointed out (J.S. at 8 n.6), Stauffer has counterclaimed against PPG Industries, Inc. ("PPG"), the company whose pesticide was registered on the basis of Stauffer's data, for enforcement of the award, and alternatively has cross-claimed against EPA for a declaration that the statute violates Article III. It also has sought cancellation of PPG's registration and damages equal to the arbitration award in the event the compensation provision were struck down.

challenge the arbitration provision. *Valley Forge Christian College v. Americans United for Separation of Church & State, Inc.*, 454 U.S. at 472; *Duke Power Co. v. Carolina Environmental Study Group, Inc.*, 438 U.S. 59, 81 (1978); *Regional Rail Reorganization Act Cases*, 419 U.S. 102, 138 (1974).

II. FIFRA'S ARBITRATION PROVISION FOR RESOLVING COMPENSATION DISPUTES IS CONSTITUTIONAL

Prior to 1978, resolution of compensation disputes between original submitters of data and follow-on registrants relying on those data was assigned to EPA. The agency's decision was subject to judicial review. § 3(c)(1)(D), 86 Stat. 979-80 (1972). In 1978, when Congress revised the FIFRA registration system, it reassigned responsibility for resolving compensation disputes to an arbitrator appointed by the Federal Mediation and Conciliation Service.[10] The arbitrator's decision was subject to judicial review only for fraud, misrepresentation or other misconduct. The substantive standard for determining compensation was unchanged by the 1978 amendments.

The district court's conclusion that the arbitration provision added to FIFRA in 1978 violates Article III rests on a misreading of *Northern Pipeline Construction Co. v. Marathon Pipeline Co.*, 458 U.S. 50 (1982). What the Court struck down in *Northern Pipeline* was the assignment of authority to adjudicate traditional common law rights to non-Article III bankruptcy judges. *See id.* at 84 (plurality); *id.* at 90 (Rehnquist, J., concurring). A compensation claim arising under FIFRA involves a statutory claim created by Congress, not a common law right. *See Monsanto*, 104 S. Ct. at 2881 & n.21. The Court's holding did not apply to statutory rights established by Congress. The plurality observed that an entirely different situation arises when Congress creates a non-Article III forum to adjudicate a substantive right created by Congress. In such a situation, Congress "may also provide that persons seeking to vindicate that right must do so before particularized tribunals created to perform the specialized adjudicative tasks related to that right." 458 U.S. at 83 (footnote omitted). The district court completely overlooked that critical distinction.

The district court objected to the statutory provision that limits judicial review of arbitration decisions to cases of " 'fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator.' " J.S. App. 20a, quoting § 3(c)(1)(D)(ii), 7 U.S.C. § 136a(c)(1)(D)(ii). According to the district court, "courts play no role in factfinding" under this provision and "are barred from considering any matters of law arising from the substantive issues in dispute in an arbitration proceeding." J.S. App. 20a. Although, as we explain below, the district court overstated the extent to which federal courts are deprived of any meaningful role under this statute, the basic flaw in that court's reasoning is its failure to recognize that this Court has upheld numerous statutes in which decisions by a non-Article III official or tribunal are not reviewable by an Article III court. *See, e.g., Andrews v. Louisville & Nashville Railroad*, 406 U.S. 320, 325 (1972); *South Carolina v. Katzenbach*, 383 U.S. 301, 333 (1966); *United States v. California Eastern Line, Inc.*, 348 U.S. 351, 354-55 (1955); *Switchmen's Union v. National Mediation Board*, 320 U.S. 297, 303 (1943). There is no constitutional requirement that every decision of an Executive Branch official must be reviewable before an Article III tribunal.

In any event, the district court also was in error when it assumed that this case presents the extreme circum-

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[10] Congress' aim was to minimize active governmental involvement in the compensation process and thereby to reduce EPA's regulatory burden. *See* 123 CONG. REC. S13095 (daily ed. July 29, 1977) (remarks of Senator Leahy); S. REP. No. 334, 95th Cong., 1st Sess. 8 (1977).

stance of an executive decision totally unreviewable in any meaningful sense in an Article III forum. To be sure, Congress sought to minimize the litigation burden on federal courts stemming from this regulatory statute, and hence authorized only a highly deferential and limited form of judicial review tailored to the typical judicial role in cases involving arbitrations. Most important, however, it preserved the judicial role to assure the integrity and fairness of the arbitration process, to prevent the arbitrator from exceeding his jurisdiction, and to protect against a manifest disregard of the law. *See, e.g., Commonwealth Coatings Corp. v. Continental Casualty Co.*, 393 U.S. 145 (1968) (undisclosed financial relationship between arbitrator and one of the parties renders award invalid); *United Steelworkers of America v. Enterprise Wheel & Car Corp.*, 363 U.S. 593, 597 (1960) (award exceeding arbitrator's authority is nonenforceable); *Wilko v. Swan*, 346 U.S. 427, 436-37 (1953) (award based on manifest disregard of the law is nonenforceable). *See also* Arbitration Act § 10, 9 U.S.C. § 10 (1982). Nothing in Article III requires a more intrusive form of judicial review.

When Congress revamped the FIFRA registration scheme in 1978, no doubt it could have left the task of resolving compensation disputes with the EPA Administrator as it had been since 1972. No serious constitutional objections could be proffered to such an agency function without casting doubt on a variety of long-standing regulatory statutes which delegate to an agency the authority to adjudicate damage or reparation claims arising under the regulatory statute.[11] Given Congress' desire to ease the burden on the EPA Administrator

[11] *See, e.g.*, Interstate Commerce Act, 49 U.S.C. § 11705(c) (1982); Communications Act §§ 207-09, 47 U.S.C. §§ 207-09 (1982); *Crowell v. Benson*, 285 U.S. 22 (1932) (agency determination of employee compensation claims against employers consistent with Article III).

without adding to that of the federal judiciary, it was not precluded by Article III from reassigning from one Executive Branch appointee (the EPA Administrator) to another (the arbitrator appointed by the Federal Mediation and Conciliation Service) the duty of resolving compensation disputes arising under this congressionally-established regulatory scheme, subject to limited judicial review.[12]

III. THE REGISTRATION SCHEME IS SEVERABLE FROM THE ARBITRATION PROVISION AND SHOULD NOT HAVE BEEN ENJOINED EVEN IF THE LATTER IS UNCONSTITUTIONAL

Section 30 of FIFRA, 7 U.S.C. § 136x, provides:

> If any provision of this Act or the application thereof to any person or circumstance is held invalid, the invalidity shall not affect other provisions or applications of this Act which can be given effect without regard to the invalid provision or application, and to this end the provision of this Act are severable.

The district court ignored this severability clause when it entered a sweeping injunction that struck down not

[12] Without any analysis or discussion of the legislative history, the district court also indicated agreement with the appellees' claim that the compensation provision constitutes a standardless delegation of power in violation of *Schecter Poultry Corp. v. United States*, 295 U.S. 495 (1935), and *Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935). J.S. App. 19a. We agree with the argument advanced by *amicus* PPG Industries in this case that the legislative history of the 1972 and 1978 amendments to FIFRA manifests an unequivocal intent by Congress to base compensation awards on a sharing of the required testing costs and that EPA, the agency charged with administering the statute, construed it in that manner at the time it had statutory responsibility for resolving compensation disputes. *See* PPG Industries, Inc. Brief as *Amicus Curiae* at 12-20. EPA's interpretation of the statute is entitled to considerable deference. *See, e.g., Chevron, U.S.A., Inc. v. National Resources Defense Council*, 467 U.S. ——, 104 S. Ct. 2778, 2782-83 (1984).

merely the arbitration provision that it had found to be invalid, but virtually the entire provision for follow-on registration of pesticides. J.S. App. 21a-22a.

Even if the district court were correct in declaring the arbitration provision unconstitutional, its injunction is far broader than necessary to eliminate the objectionable portion of the statute and plainly is incompatible with the presumption established by the severability clause that "Congress clearly intended 'the remainder of the Act' to stand if 'any particular provision' were held invalid." *INS v. Chadha*, 462 U.S. 919, ——, 103 S. Ct. 2764, 2774 (1983). Nothing in the statute or legislative history suggests that Congress intended the validity of the follow-on registration provision to depend on the validity of its chosen forum for resolving compensation disputes. Indeed, there is every indication that registration of pesticides was Congress' first priority, and that the registration scheme is not to be held hostage to the mechanics of compensating the original data submitter.

First, the arbitration provision was not part of the original follow-on registration scheme enacted by the 1972 amendments, but rather was grafted onto the scheme in 1978. The shift of responsibility to resolve arbitration disputes from EPA to arbitrators to ease the burdens placed on EPA was only a minor element of the 1978 amendments; their major focus was to reinvigorate and streamline the follow-on registration program which had become an "administrative nightmare in which the process of registering new pesticides simply [had] ground to a halt." *Chevron Chemical Co. v. Costle*, 641 F.2d 104, 111 (3d Cir.), *cert. denied*, 452 U.S. 961 (1981); *see also Monsanto*, 104 S. Ct. at 2868-69.[13] There is utterly no

[13] According to the Senate Committee Report:

> The single largest problem is the fact that the registration and reregistration process has ground to a virtual halt. The registration process is the foundation of the entire pesticide program. This problem has impacted upon the structure of the industry, the availability of pesticides, and overall implementation of the Act.

S. REP. No. 334, 95th Cong., 1st Sess. 3 (1977).

basis for assuming that Congress "'would not have enacted those provisions which are within its power [*i.e.*, the follow-on registration provision], independently of that which [the district court held] is not'" within its power (*i.e.*, the assignment of responsibility for fixing compensation to federally-appointed arbitrators). *Buckley v. Valeo*, 424 U.S. 1, 108 (1976), quoting *Champlin Refining Co. v. Corporation Commission*, 286 U.S. 210, 234 (1932). In light of this sequence of events, the district court should have severed the arbitration provision from the balance of the statute, and under *Frost v. Corporation Commission*, 278 U.S. 515 (1929), could have revived the provision that assigned to EPA responsibility for fixing compensation that the arbitration provision had superseded.

Second, while Congress plainly regarded the availability of compensation as an important element of the regulatory scheme, it also left no doubt that its paramount aims were to promote competition in the pesticide industry and to eliminate wasteful duplication of testing by prompt implementation of the follow-on registration program. To assure that the registration program would not be held hostage to the compensation process, Congress specifically provided in the statute that "[r]egistration action by the Administrator shall not be delayed pending the fixing of compensation." § 3(c)(1)(D)(ii), 7 U.S.C. § 136a(c)(1)(D)(ii). It is difficult to conceive of a clearer statement of Congress' intent that the mechanics of compensation not interfere with prompt registration of competitive pesticides found to be safe and effective.[14]

[14] The Senate Committee Report stressed that controversies over data compensation should not be permitted to undermine the regis-

Third, Congress included in the statute a broad grant of jurisdiction to district courts "specifically to enforce, and to prevent and restrain violations of" FIFRA. § 16(c), 7 U.S.C. § 136n(c). If, as the district court believed, the principal constitutional objection to the arbitration provision was the lack of adequate judicial review by an Article III court, the district court could have remedied the constitutional objection with minimum violence to the surrounding statute simply by removing the offending language limiting judicial review. The result of such a careful excision would have been to permit arbitration awards to be enforced or enjoined under the district courts' residual jurisdiction under § 16(c) or, alternatively, under 28 U.S.C. § 1331 (1982) or 28 U.S.C. § 1337(a) (1982).[15] *See International Association of Machinists v. Central Airlines, Inc.*, 372 U.S. 682, 696 (1963). This remedial approach would have been faithful to the district court's duty "to save and not to destroy" the remaining portions of the statute. *Tilton v. Richardson*, 403 U.S. 672, 684 (1971) (plurality), quoting *NLRB v. Jones & Laughlin Steel Corp.*, 301 U.S. 1, 30 (1937).

The district court below addressed none of these factors. It provided no explanation for its failure to apply the presumption favoring severability stemming from the severability clause in this statute, and also ignored the further presumption that a provision is severable "if what remains after severance 'is fully operative as a law.'" *INS v. Chadha*, 103 S. Ct. at 2775, quoting *Champlin Refining Co. v. Corporation Commission*, 286

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tration program. "Since registration is critical, this program must be made to work." S. REP. No. 334, 95th Cong., 1st Sess. 3 (1977).

[15] Section 1331 confers original jurisdiction on district courts in "all civil actions arising under the . . . laws . . . of the United States." Section 1337(a) similarly confers original jurisdiction on district courts in a "civil action or proceeding arising under any Act of Congress regulating commerce . . . ."

U.S. 210, 234 (1932). Whether the proper remedy is to strike the arbitration provision and restore EPA's pre-existing duty to fix compensation awards or to strike the limitation on judicial review, the balance of the statute in either case is fully workable as a regulatory scheme. Accordingly, if this Court agrees with the district court that the compensation provision in § 3(c)(1)(D) is incompatible with Article III, the Court should modify the district court's injunction to preserve the unobjectionable portions of the statute.

IV. INVALIDATION OF THE FIFRA REGISTRATION SCHEME WILL THWART CONGRESS' GOAL OF PROMOTING COMPETITION IN THE SALE OF PESTICIDES AND ELIMINATING WASTEFUL DUPLICATION OF SCIENTIFIC TESTING

The 1978 version of the FIFRA registration scheme reflects the coalescing of four important public objectives. First, Congress established a regulatory mechanism intended to assure that only safe and effective pesticides are sold in interstate commerce. Second, by authorizing EPA to rely on data in its own files, Congress hoped to streamline the regulatory process, and thereby to eliminate waste and duplication of effort and to speed up the registration of pesticides. Third, by establishing a mechanism to compensate registrants whose data are used in approving follow-on registrations, Congress chose to spread the cost of assembling the data among all registrants that benefitted from the data. It thereby sought to minimize possible disincentives to innovation if initial registrants had to bear the entire cost of a registration application while potential competitors enjoyed a "free ride" on the initial registrant's costly studies. In addition, by assigning the resolution of compensation disputes to arbitrators instead of to courts or to EPA, Congress sought to minimize the burden of dispute resolution on the agency and the judiciary. Finally, to minimize barriers to market entry resulting from the data submission

requirements and thus promote competition, Congress reaffirmed the agency's right to use data in its files to approve follow-on applications for products the agency had already found to be safe and effective.[16]

The industry's evolution demonstrates that Congress designed a regulatory scheme tailored to achieve these goals. As Congress predicted, § 3(c)(1)(D) has removed unnecessary barriers to market entry created by the Act's data submission requirement and has facilitated the emergence of a competitive market environment. EPA still must examine each proposed pesticide product to confirm its safety and efficacy, but it no longer must ignore pertinent information in its own files. Similarly, registration applicants for follow-on products no longer must conduct years of costly studies to prove again and again what EPA already can determine from data in its files.

Most competition in this industry comes from follow-on products. For example, of approximately 60 companies that have a registration for a four pound per gallon methyl parathion product, at least 90% (including Drexel and Griffin) hold follow-on registrations. Similarly, of the dozen or so companies that market a three pound per gallon dinitro product, at least two-thirds (including Drexel) hold follow-on registrations.

The approval of a follow-on application can produce almost immediate economic benefits to farmers and the public in the form of reduced prices, often even before the follow-on product reaches the market. For instance, through 1983, the Diamond Shamrock Corporation, a multinational conglomerate with annual sales of over $3 billion, had been the only registrant of technical chlorothalonil, a fungicide used on most of the American pea-

[16] *See, e.g.*, S. REP. No. 334, 95th Cong., 1st Sess. 30-31 (1977); 123 CONG. REC. H11856 (daily ed. Oct. 31, 1977) (remarks of Rep. Foley); 123 CONG. REC. S13091, S13093-95 (daily ed. July 29, 1977) (remarks of Senator Leahy); 124 CONG. REC. S15303-04 (daily ed. Sept. 18, 1978) (remarks of Senator Leahy).

nut crop, on soybeans and on various vegetables. Diamond Shamrock had held patents on chlorothalonil and hence had faced no competition in the sale of the product.[17] Griffin obtained a registration for technical chlorothalonil in January 1983. Until that time, Diamond Shamrock's product sold for approximately $23 per gallon wholesale. However, since Griffin received its registration, Diamond Shamrock has dropped its price to under $20 per gallon—approaching the $15 per gallon price at which the product is offered in at least one foreign market. American farmers will save millions of dollars per year as a result of the more competitive price structure that has emerged for this product since Griffin positioned itself to enter this market.[18]

The price for atrazine, which is used on approximately 64 million acres of crops in this country, also has dropped since follow-on registrations have been issued. In 1976, before the patent held by Ciba-Geigy Corporation expired, the wholesale price of atrazine 4-L (a formulated product) was approximately $13 per gallon. Since then, at least eight follow-on registrations have been issued (including one each to Griffin and Drexel), and the price has dropped to below $7 per gallon. With about 40 million pounds of product used each year, this price reduction has yielded enormous cost savings for this country's farmers.

A price reduction also is likely in the domestic trifluralin market during 1985 when the patent held by an Eli Lilly & Company subsidiary expires. This pesticide is used in the United States primarily on cotton and soybeans and also is sold abroad. In the United States, trifluralin is sold to distributors for approximately $21 to $23 per gallon (assuming a formulation of four pounds

[17] EPA, Office of Pesticide Programs, *Agricultural Impact Analysis of Chlorothalonil* at 5 (Sept. 28, 1983).

[18] *Id.* at 9. As EPA recognizes, price decreases are likely when a pesticide company suddenly faces competition after having been "isolated . . . by patent or other similar protection." *Id.* at 7.

per gallon), while the price abroad, where multiple sellers compete with each other, is approximately half of the domestic price. Drexel already has received a trifluralin follow-on registration from EPA and expects to begin marketing its product in 1985 or 1986, after Eli Lilly's patent expires. Lilly already has dropped its domestic price over 15 percent from 1983-84 levels in anticipation of increased competition, and the price can be expected to drop further after Drexel and others enter the market. The impact of this decrease will be widespread. In 1982 alone, approximately 53 million pounds of trifluralin were produced in the United States.[19]

If the Court affirms the decision below and invalidates the follow-on scheme, there appears to be no question that many initial registrants will seek to cancel existing follow-on registrations. For example, as previously noted, Stauffer chemical has sought cancellation of PPG's follow-on registration of butylate in the post-arbitration litigation pending in the District of Columbia. *See* note 9 *supra*. Similarly, Eli Lilly has brought lawsuits against Drexel and other firms possessing "follow-on" trifluralin registrations seeking to have those registrations declared invalid. *See, e.g., Eli Lilly & Co. v. EPA*, No. IP831858C (S.D. Ind. filed Nov. 21, 1983). Plainly, there would be little incentive for initial registrants to agree to license their data to follow-on applicants—the only portion of the registration scheme not enjoined by the district court (J.S. App. 22a)—because the effect of doing so would undercut the initial registrant's dominance of the market and the resulting non-competitive price structure.

In the face of cancellations of existing follow-on registrations and the inability to obtain new ones, the only

[19] *See also* EPA, OFFICE OF RESEARCH & DEVELOPMENT, GUIDELINE FOR THE DISPOSAL OF SMALL QUANTITIES OF UNUSED PESTICIDES at 161, table C (1975) (the atrazine production volume in the United States in 1971 was 25 million pounds).

option available to firms wishing to compete vigorously with the initial registrants would be to duplicate the data already in EPA's files. This wasteful duplication would frustrate one of Congress' principal aims in enacting the 1978 amendments.[20] In any event, the option may be more theoretical than real because duplicating the data rarely would be economically feasible. Approximately half of Drexel's principal pesticide products, for example, have follow-on registrations issued since 1978. These include both technical and formulated, "end-use" products; if the company now were required to spend approximately $1.8 to $2.9 million per active ingredient to generate data to support only its technical registrations,[21] it could have to spend over $6 million, 20 percent of the company's annual sales volume.

Furthermore, Drexel expects to file between 15 and 20 applications for new follow-on registrations in the next several months and Griffin plans to file between 10 and 12. If EPA is enjoined from processing these applications by relying on previously submitted data, those companies' costs of data assembly could be prohibitive. Moreover, these companies' circumstances are hardly unique. In papers filed with this Court in the *Monsanto* case, EPA estimated that over the course of a year, applications for 1,700 to 2,200 new products will be precluded or delayed if implementation of the registration scheme is enjoined.[22]

[20] *See* S. REP. No. 334, 95th Cong., 1st Sess. 30-31 (1977).

[21] *See* note 2 *supra*. Indeed, EPA's estimates appear in many cases to be low. For example, to support their maneb registrations, Drexel and Griffin face an estimated cost of $4.6 million simply to produce additional data requested by EPA as part of its "data call-in program" pursuant to § 3(c)(2)(B), 7 U.S.C. § 136a(c)(2)(B). If each company were compelled to obtain a totally new registration and pay for all testing itself, it could have to pay this sum plus the $1.8 to $2.9 million data cost estimated by EPA.

[22] Affidavit of Edwin L. Johnson, Director, EPA Office of Pesticide Programs, submitted in support of EPA's Application for a

Furthermore, these are not tests that can be duplicated overnight; many are extremely time consuming, including some that will take as long as four years to complete.[23] This delay in obtaining registrations will handicap the smaller companies seeking to return to the market because of the substantial headstart gained by the few large firms that already have received registrations based on their own data. EPA has estimated that less than 25 percent of the anticipated registration applications for new agricultural pesticides or amendments thereto are likely to qualify for registration if the follow-on registration scheme were invalidated.[24]

Finally, sharp price increases are almost certain to follow a decision that results in the cancellation of existing follow-on registrations. This will occur in two ways. First, registrants who have submitted data, no longer facing competition from follow-on sellers, will be able to raise their prices with impunity.[25] Second, even if some of the small pesticide firms can afford to sponsor their own tests and eventually return to the market, the cost of market reentry will be substantially higher than at present, forcing them to set their own prices at significantly higher levels than they do today.

In sum, the sharp decline in competition that inevitably would follow invalidation of the 1978 amendments would

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Stay of Judgment of the United States District Court for the Eastern District of Missouri Pending Direct Appeal, July 1983, ¶ 6, *Ruckelshaus v. Monsanto Co.*, 463 U.S. 1315 (1983).

[23] *Id.* ¶ 5.

[24] *Id.* ¶ 6.

[25] For example, in today's market, over 40 million pounds of 2, 4-dichlorophenoxyacetic acid are applied annually on grain crops such as corn, wheat, barley, rye and oats, and some two dozen firms hold follow-on registrations. If these firms are forced out of the market because their follow-on registrations have been cancelled, the data submitters for those products will be free to raise their prices substantially.

affect not only the viability of most small pesticide companies, but also, in turn, would increase the costs of American farmers and the prices they charge for their products. Nothing in Article III compels such a calamitous result. To the contrary, Congress acted reasonably in enacting § 3(c)(1)(D) of FIFRA under its broad Commerce Clause authority to prevent such consequences, while at the same time assuring the original data submitter a fair and rapid mechanism for obtaining compensation without unduly burdening the courts or EPA.

CONCLUSION

The district court's judgment should be reversed and the case remanded to that court with directions to dismiss the complaint.

Respectfully submitted,

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